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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/056,806	04/08/1998	ARNO N VERMEULEN	I/97272	5753

7590 10/29/2003

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EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
1647	23

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/056,806	VERMEULEN ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,18,19 and 21-32* is/are pending in the application.

4a) Of the above claim(s) *6-11,18,21-26,29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12-15,19,27,28,30 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15,18,19 and 21-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

1. As noted previously, Finality of the Office Action of 5-20-02 has been withdrawn for consideration of the amendment filed 3-21-02 which crossed in the mail.

2. The amendments filed 2-21-02 and 3-21-02 have now been entered into the record and have been fully considered. Claims 1-15, 18-19, and 21-32 are pending.

3. Claims 6-11, 18, 21-26, 29 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 4.

4. This application contains claims 6-11, 18, 21-26, 29 and 31 drawn to an invention nonelected without traverse in Paper No. 4. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

5. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

6. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year

prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-5, 12-15, 19, 27, 28, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by EP0382531, Gurnett, 16.08.90., or in the alternative, under 35 U.S.C. 103(a) as obvious over EP0382531, Gurnett, 16.08.90.

Applicants amendment of 3-21-02 introduces the limitation wherein the extract is of total Eimeria sporozoites. Applicant's specification at pp. 23 discloses the purification of sporozoites via 0.4% taurocholate and purification via nylon wool passage followed by Triton X-114 detergent extraction. Applicant's argue that the amendment distinguishes the composition of claim 1 in that the composition of Gurnett is prepared via a different procedure and is of a detergent extract of sporozoite lysates. Applicants thus conclude that Gurnett does not anticipate the claimed invention.

Applicant's arguments filed 3-21-02 have been fully considered but are not persuasive. Gurnett teaches at pp. 4, lines 24-33, sporozoite purification from pelleted sporocysts via excysting solution of .25% trypsin, 4% taurodeoxycholic acid and 10 mM MgCl2 with incubation at 41 degrees Celsius for about 60 minutes. The released sporozoites are then collected by centrifugation and washed in PBS, resuspended in Percol and centrifuged again followed by washing in PBS and collection via centrifugation. The sporozoites were then lysed by sonication in water and subjected to either Triton X-114 extraction with or without lipase, see in particular p. 5, line 2 and lines 12-40. Thus, the purification steps of sporozoites are similar and result in the same composition of purified sporozoites, with the exception that the Gurnett reference sonicates the sporozoites prior to Triton extraction whereas the instant application extracts the purified sporozoites without prior sonication. The prior art teaches a hydrophilic phase of a tertoctylphenoxypoly (ethoxyethanol) (triton x-114) extract of Eimeria oocysts, sporulated oocysts and sporozoites. The reference teaches that membrane bound proteins may partition into the hydrophilic phase upon lipase

treatment and that such a composition is immunoprotective. Thus, the reference teaches the elements of non-membrane bound (hydrophilic) proteins but also teaches the addition by lipase treatment of particular membrane bound proteins separated from the membrane via lipase treatment. While, the Gurnett reference uses different steps to arrive at the composition there is no apparent step which serves to remove sporozoite proteins prior to the Triton X-114 extraction. Thus, even though the Gurnett reference teaches extraction of sporozoite lysates, this step is not deemed to materially change the components of the lysates from "total" sporozoites as newly claimed. The Gurnett lysates are of total sporozoites and all constituents are contained in the Triton extraction. In other words, simply because the Gurnett reference teaches the extraction step upon lysed sporozoites does not negate that all total proteins are provided to the extraction as claimed. For there to be a difference between the prior art product and applicants product as newly claimed there must be some distinguishable difference in the composition and not the method by which it is prepared. There is no evidence to conclude that preparations of total sporozoites either with or without the lysing step via sonication would change the material product and the Patent Office has insufficient resources to test whether or not the sonication step results in any material difference of the product claimed from the prior art. Thus, the burden shifts to applicant to show unobvious difference. The Gurnett reference teaches the immunoprotective nature of the compositions so prepared and which correlate to instant claims. It is noted that the molecular weight determination of the four major glycolipid linked proteins from E. tenella sporozoites prepared via such methods as demonstrated in Examples 5 and 6

(see also Table II) reveal that the proteins which may be isolated either in the hydrophilic fraction (when lipase is added prior to phase separation) or the hydrophobic fraction (when lipase is added after phase separation) share the desired molecular weight characteristics of applicants claims. As the evidence shows that the disclosed proteins may be isolated from either the hydrophilic phase of a triton X-114 detergent extraction with lipase, or the hydrophobic phase of a triton X-114 detergent extraction, the disclosed peptide compositions of Gurnett cannot be distinguished from the compositions and vaccines claimed as the preparations are both originated from total sporozoite protein. The Gurnett preparation is protective against Eimeria coccidiosis. The Gurnett reference teaches the vaccine compositions for vaccination with carriers, and with adjuvant, see in particular p. 3, line 40, p. 5, lines 46-48 and p. 7, lines 27-45. For immobilization or labeled compositions, see in particular Examples 1-12.

As in MPEP 2111.03, Applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte,* 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman,* 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

10. Claims 14 and 28 stand rejected as set forth in Paper No. 16, mailed 9-5-01, under 35 U.S.C. 103(a) as being unpatentable over EP0382531, Gurnett et al., 16.08.90, MacKenzie et al., US4,981,684, Jan. 1, 1991 and Estrada et al., US 5,597,807, Jan. 28, 1997.

Applicant's arguments are believed to be essentially as above, in particular applicants argue that if the independent claims are nonobvious that the dependent

claims are nonobvious.

Applicant's arguments filed 2-21-02 and 3-21-02 have been fully considered but are not persuasive. The base claim appears properly rejected absent evidence that the introduction of the additional steps would materially change the characteristics of the claimed invention. It is noted that the Gurnett preparation is useful for vaccination purposes as is claimed. Thus, for the aforementioned reasons the rejection is maintained.

Gurnett et al., is set forth above and teaches the composition of claim 1 and vaccine compositions with carrier and adjuvant.

Gurnett et al., fail to teach the composition wherein the adjuvant is Quil A.

MacKenzie et al., teach as of 1991 the knowledge of one of skill in the art who recognized the use of adjuvant complexes, specifically where the glycoside is Quil A (Quillaja saponin) for use in the formulation of vaccines suitable for immunization against pathogens including Eimeria, see in particular Abstract, column 2, lines 43-44 and column 3, line 47.

Estrada et al., similarly teach that as of 1-28-97 (prior to applicants invention) that Quillaja saponins, (Quil A) are especially advantageous to the promotion and production of isoform specific immunoglobulin, specifically IgG and IgA antibodies which enhance both humoral and secretory immune responses in invertebrates, see in particular columns 5-6, General Methods. Estrada also particularly points to the use of Quillaja saponins in Eimeria vaccine preparations, see in particular column 6, line 30.

Thus, it would have been prima facie obvious to one of skill in the art at the time

of invention to modify the vaccine of Gurnett et al., using the adjuvant Quil A to provide for the advantageous and superior benefits of stimulating IgG and IgA antibodies against the Eimeria antigens for the purpose of producing protective immunity in mammalian hosts. The skilled artisan would have motivation to do so and would have expected positive results given the teachings of Gurnett, MacKenzie and Estrada as set forth above and as exemplified in the various references. Thus, the cumulative reference teachings render the claimed invention obvious to the skilled artisan.

Status of Claims

11. No claims are allowed.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Sharon L. Turner, Ph.D.

10/28/03